

REMARKS

Applicants respectfully request reconsideration of the present application for the reasons as set forth below.

In the most recent Official Action, the Examiner maintains an objection to the claims under 35 U.S.C. §112 despite the fact that the pertinent part of the claims which set forth that there is a surface contacting portion below an opening by which the sample contacts the front surface of a test strip located in the test card is clearly disclosed in the specification. This portion of the present specification could not be made any more clear such as by Fig. 9 and the description that the liquid specimen travels through the opening "to contact the absorbent" in conventional test strips, such as described at page 12 of the application. The Examiner's only position as to why this is not completely disclosed in the specification appears to be his contention that "test strips have a broad range of possible designs" and thus the specific design as set forth in the claims is somehow not disclosed in the specification. This position is totally untenable for the reasons set forth below.

In the first place, the description of the specification unambiguously discloses a flat test strip which is placed in the Applicants' test card in such a manner that a surface contacting portion on its flat surface lines up with an opening in the test card. Secondly, the Examiner's position concedes that the embodiment of a flat test strip is one of the possibilities with regard to the configuration of the conventional test strip as was disclosed in Applicants' specification. Under well established patent law, the description of a test strip which may be subject to different but conventional embodiments provides support for the inclusion of any of the supported embodiments in the claims.

The Examiner's rejection of the claims under 35 U.S.C. §112 is thus respectfully traversed and should be withdrawn.

In the Official Action, the Examiner rejected Claims 16-19 as being unpatentable over May et al. in view of Sun et al., and further in view of Boger et al. US 4,518,565, These rejections are respectfully traversed for the reasons that follow.

In short, the Examiner seems to have reached the conclusion that the May reference discloses the specific claimed embodiment of the present invention wherein a sample is introduced through an opening on a test card which is directly over a front surface of the test strip housed within, as opposed to contacting the test strip at the edge which is what is disclosed in the may reference. Instead, the May reference **teaches away** from the present claims because it covers up in all cases the front surface of the test strip and **prevents** the sample from contacting the test strip on the front surface. Quite simply, the May reference (as well as the cited Sun reference) discloses a test card wherein there is a sample opening exposing the end of a porous member through which the specimen must pass before it can even contact the absorbent part of the test strip, and thus only provides embodiments wherein the lower edge of a test strip is contacted with the fluid sample. There is thus no disclosure or suggestion in the May (or Sun) reference of the presently claimed invention.

Moreover, the Examiner cites the Boger et al. reference for the fact that Boger shows "ridges or other means which facilitate the preferred parallel alignment of the strips". However, Boger is totally unrelated to the present invention and does not disclose or suggest **any** immunoassay test strip whatsoever. Instead, Boger involves applying the test sample to a reagent pad or spot, a wholly different test than the immunoassay conducted in accordance with the test card of the present application.

Accordingly, neither May, Sun or Boger disclose or suggest applying a test sample directly on the face of an immunoassay test strip in which the test sample then moves by capillary action to the test portion of the test strip. Applying the test sample to the front surface of the test strip per Applicant's invention significantly reduces the time required for sample to reach the test portion and thus reduces time required to get the test results. The present invention thus provides significant advantages not previously obtained using the failed methods of the prior art.

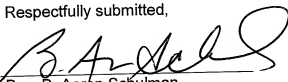
In addition, further evidence of the non-obviousness has been shown in the fact that the claimed invention has achieved commercial success. Previously, Applicants submitted the Declaration of Keith Palmer (copy attached) which evidenced that the test card which embodies the claimed invention has achieved a great deal of commercial success. Further, the Assignee of the present application, American Bio Medica Corporation, continues to sell this test card, and it continues to this day to be a commercially successful product. Accordingly, in addition to the fact that the prior art teaches away from the present invention, the secondary considerations of commercial success and the achievement of long unmet needs in the industry also compel the conclusion that the present claims are indeed unobviousness over the cited prior art.

The Examiner's rejections of the claims on the basis of the combination of the May and Boger references, insofar as applied to the claims as amended, are thus respectfully traversed and should be withdrawn.

In light of the foregoing amendments and arguments, Applicants respectfully submit that the pending claims overcome all of the Examiner's rejections and have been placed in condition for immediate allowance. Such action is respectfully requested.

Respectfully submitted,

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